

REMARKS

The Office Action of July 7, 2009, has been received and reviewed. Claims 1 and 6-11 stand rejected. This application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Basis for the amendments, and for new claims 22 and 23, can be found throughout the application, for example, at [0019]; [0022]; [0025]; [0026]; **Example I**; and **Example II**. No new matter has been presented. Reconsideration is respectfully requested.

Priority

The present application continues to claim priority to U. S. Patent Application Serial No. 09/549,463, filed April 14, 2000, now U.S. Patent 6,855,544 B1, U.S. Provisional Patent Application Serial No. 60/129,452, filed April 15, 1999, PCT International Patent Application No. PCT/EP2003/007690, filed on July 15, 2003, designating the United States of America, and published, in English, as-International Publication No. WO 2004/009618A2 on January 29, 2004, U.S. Provisional Application No. 60/397,066, filed July 18, 2002, co-pending International Patent Application No. PCT/EP03/50201, filed May 27, 2003, designating the United States of America, European Patent Application No. 02077953.4, filed July 18, 2002, and U.S. Provisional Application No. 60/397,066, filed July 18, 2002.

The Office noted in the Office Action of July 7, 2009, that a certified copy of priority application European Patent Application No. 02077953.4, filed July 18, 2002, has not been filed, as required by 35 U.S.C. 119(b). *Id.*, at page 2. Consequently, applicants will provide a certified copy to the Office as soon as it is available. Also, the Office noted that "Applicant must file a petition for an unintentionally delayed priority claim." *Id.*, at page 3. Applicants have filed such a Petition in the Office concurrently with the present Amendment, a courtesy copy of which is provided herewith.

Objection to the Specification

The Specification stands objected to as containing a priority reference to an application to which priority has not yet been recorded. Applicants duly note the objection, and respectfully submit that the objection will become moot when the petition for an amended priority right under

37 C.F.R. § 1.78(a)(3) and 37 C.F.R. § 1.78(a)(6) is granted.

Oath/Declaration

The Examiner asserts that the Oath/Declaration filed in the parent application is defective as, “Although the new declaration identifies a foreign application for patent or inventor’s certificate on which priority had been claimed, such a claim has not been made pursuant to 37 CFR 1.55, and as such is without effect.” Office Action of July 7, 2009, at page 4. As detailed above, the attached certified copy of European Patent Application No. 02077953.4, and applicants’ pending Petition for Acceptance of an Unintentionally Delayed Priority Claim, will render this objection moot.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1 and 6-11 stand rejected under 35 U.S.C. 112, first paragraph, as assertedly failing to comply with the written description requirement. Specifically, the Office has asserted, “There is no support on the specification for integrating the IgA molecule into the cell’s genome.” Office Action of July 7, 2009, at page 4. Applicants respectfully traverse this rejection, as hereinafter set forth.

Applicants introduced the rejected language in response to an indefiniteness rejection under 35 U.S.C. § 112, second paragraph. As applicants remarked in the Amendment of May 29, 2007, applicants disagree that the metes and bounds of “stable” transfection are unclear. As recited in the Specification, “stable clone(s) () can be selected and propagated according to standard procedures known to the person skilled in the art.” *Id.*, at [0016]. There are few techniques in molecular biology better understood than the difference between stable transfection and transient transfection. The Office has provided no evidence to contradict the clarity of this art-recognized concept and terminology.

In any case, applicants have herein amended independent claims 1 and 8 to remove the presently rejected language (integrating the IgA molecule into the cell’s genome), and to recite the claimed cell “comprising a selective marker,” and “wherein stable transfection may be determined by selecting those transfected human embryonic retinoblast cells capable of surviving growth in a media selective for the presence of the selective marker for a predetermined amount

of time.” There is abundant support in the Specification for the production of stable transfection of host cells through the use of Geneticin (G418) selection. See, e.g., [0035] (selection of stable transformants by culture in Geneticin for 3 weeks). New claims 22 and 23 do not recite “stable” transfection. Thus, at least as amended, the pending claims comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 6, and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Gao *et al.* (2004) U.S. 6,821,512 B1 (hereinafter “Gao”) in view of Hateboer *et al.* (2000) WO 00/63403 A2 (hereinafter “Hateboer”). Applicants respectfully traverse this rejection, as hereinafter set forth.

As clarified in the amended Specification, the present application claims priority to U.S. Provisional Patent Application Serial No. 60/129,452, filed April 15, 1999, through U. S. Patent Application Serial No. 09/549,463, filed April 14, 2000, now U.S. Patent 6,855,544 B1, of which the present application is a continuation-in-part. Gao has an earliest possible effective date of December 3, 1999 (the filing date of provisional application No. 60/169,025). Hateboer has an earliest possible effective date of April 15, 1999 (the priority date of EP 99201176.7). Therefore, neither reference precedes the priority date of the present application, and cannot constitute prior art for the purpose of supporting a rejection under 35 U.S.C. § 103. Thus, applicants submit that upon allowance of their Petition for Acceptance of an Unintentionally Delayed Priority Claim, which has been submitted contemporaneously to the Office with the present Amendment, the rejection under 35 U.S.C. § 103(a) in view of Gao and Hateboer cannot stand.

Rejoinder

Applicants respectfully request rejoinder of claims 12 and 14-20. If an applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all elements of the allowable product claim will be rejoined. MPEP § 821.04; See also In re Ochiai, 71 F.3d 1565 (Fed. Cir. 1995); In re Brouwer, 77 F.3d 422 (Fed. Cir. 1996). Applicants respectfully submit that claims directed to a product (*e.g.*, claim 1) were previously elected by applicants. Applicants further note that

claims 12 and 14-20 include all the elements of product claim 1. In addition, applicants respectfully submit that product claim 1 is in condition for allowance. As such, applicants respectfully request rejoinder of process claims 12 and 14-20, which include all elements of an allowable product claim.

Nonstatutory double patenting rejection

Claims 1, 6, and 7 stand rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1, 3, 6-7, and 9 of U.S. Patent No. 7,429,486 ('486 Patent). Further, claims 1, 6, and 7 stand rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1, 2, and 5-7 of U.S. Patent No. 7,262,028 ('028 Patent). Applicants respectfully request these nonstatutory obviousness-type double patenting rejections be held in abeyance. Should this be the only remaining issue precluding patentability, applicants reserve the right to file appropriate terminal disclaimers.

In view of the present Amendment and Petition for Acceptance of an Unintentionally Delayed Priority Claim, the application should be in condition for allowance, and prompt notice thereof is respectfully solicited. If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'D. Morath', with a long horizontal flourish extending to the right.

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ATS

Enclosure: Copy of Petition for Acceptance of Unintentionally Delayed Priority Claims